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Small Business Innovation Research (SBIR/STTR) Program: Government-funded R&D for fun and profit

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Small Business Innovation Research (SBIR/STTR) Program

*Government-funded R&D
for fun and profit*

Presented to UMASS Medical School
8 February 2012

Natalie S. Rudolph, Ph.D.
Rudolph Biomedical Consulting

Outline of Presentation

1. Background
2. Strategic use of SBIR funds
3. “Fast-Track” program
4. Application process
5. Review process
6. Conclusions
7. Information sources

1. Background



Uncle Sam wants *YOU*!



The U.S.
government is
looking for a few
good companies ...

Guess how much...



... money the U.S.
government invests
in technology R&D
by small
businesses?

Features of SBIR Program

High risk, innovative ideas with commercial potential
Reauthorized through Sept. 2017

- SBIR: Small Business Innovation Research
 - Small company conducts R&D for new technologies
 - PI has primary employment with proposing company
 - $\geq 66\%$ of work done by the company
- STTR: Small Business Technology Transfer Research
 - Cooperative R&D between small company and non-profit institution
 - Award goes to company, PI may be from company or partner
 - $\geq 40\%$ of work at business, $\geq 30\%$ at non-profit partner

What will SBIR funding do for you?

1. Provide seed money for high-risk innovative projects to start or expand a business
 - Up to \$1M+ per project in direct & indirect costs
 - No repayment, full equity ownership
 - Company retains rights to intellectual property
2. Fund collaborations & consultants
3. Add recognition, credibility, validation and visibility
4. Leverage grant to attract other capital

Three-phase Program

- Phase I
 - *No preliminary data needed (**)*
 - Feasibility study
 - SBIR: \$150K+ for 6 months
 - STTR: \$100K+ for 12 months
- Phase II
 - Full R&D program
 - 2-Year Award, \$1M (SBIR) or \$750K (STTR)
 - Only successful Phase I projects can apply
- Phase III
 - Commercialization Stage
 - Non-federal support

Massachusetts SBIR Success

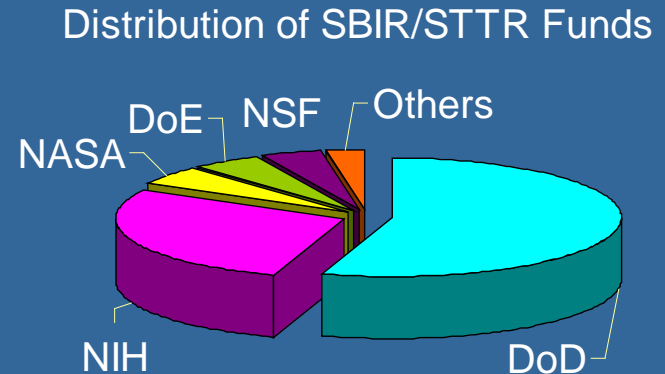
- Massachusetts ranks #2 after California in total funding
 - 2010: 843 total active awards worth \$292M
 - DoD 2010: 459 awards worth \$137M
- Worcester, 2008-2011: 28 awards worth \$21M

SBIR Program Eligibility

- Organized for-profit U.S. business
- ≤ 500 employees
- $\geq 51\%$ owned by U.S. citizens
 - Or: $\geq 51\%$ owned by 1 other company that is $\geq 51\%$ owned by U.S. citizens
- Small business located in the U.S., work done in U.S.
- Can “bootstrap” a company but not fund a “virtual” company
 - PI is $\geq 50\%$ employee of proposing business and does not have another full-time job
 - Company has its own facilities at time of award

Who Funds SBIR Awards?

1. Dept. of Agriculture (USDA)
2. Dept. of Commerce (DOC)
3. *Dept. of Defense (DOD)*
4. Dept. of Education (ED)
5. Dept. of Energy (DOE)
6. *Dept. of Health and Human Services (DHHS)*
 - *National Institutes of Health (NIH)*
7. Dept. of Transportation (DOT)
8. Environmental Protection Agency (EPA)
9. National Aeronautics and Space Administration (NASA)
10. National Science Foundation (NSF)
11. Dept. of Homeland Security (DHS)



Two Largest SBIR Programs

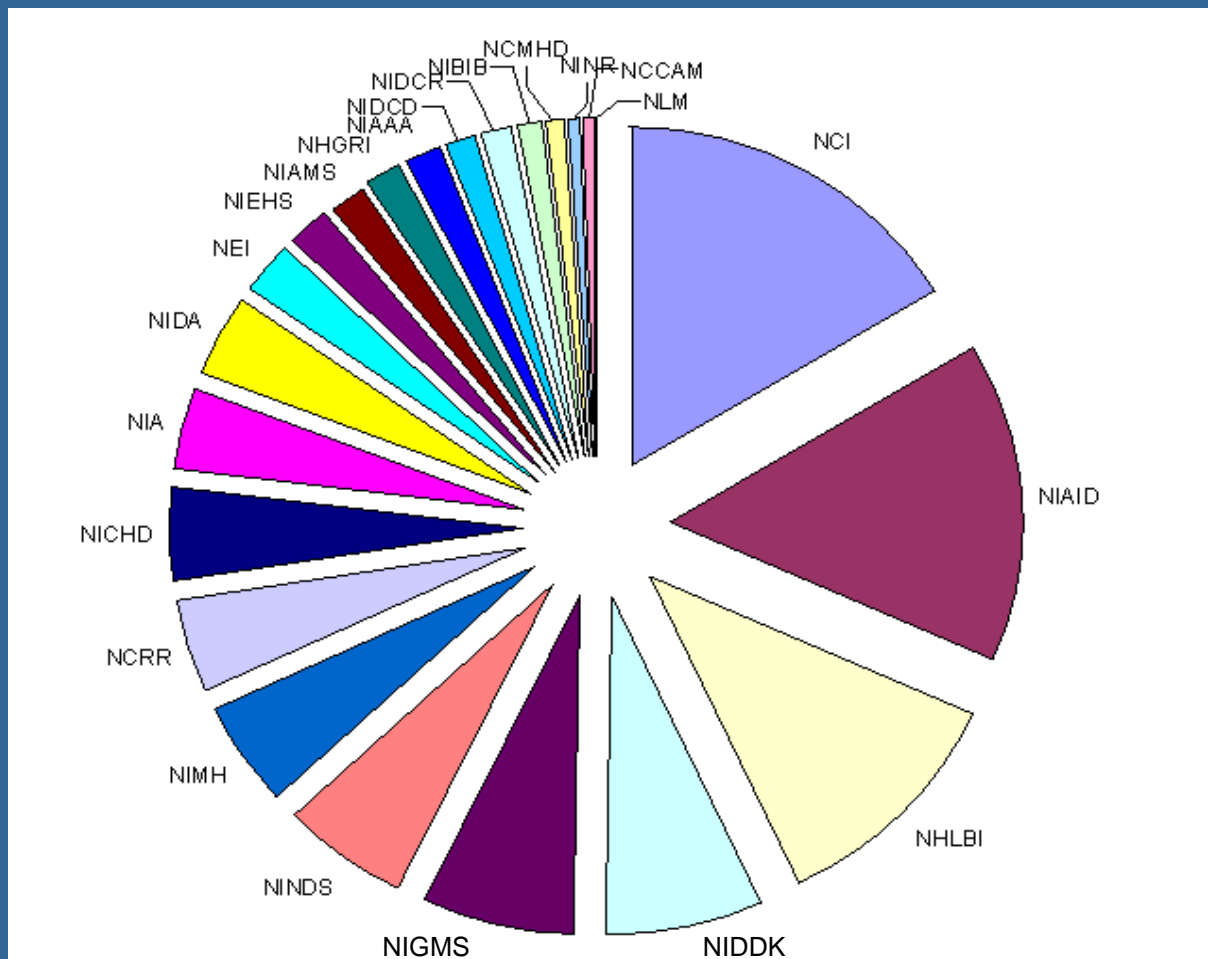
1. DoD: Contracts

- Each solicitation list topics and deliverables
- Funds highly innovative “way-out-there” approaches to military problems – including biomedical challenges
- Deadlines announced each year
- Agency staff review of proposals

2. NIH: Mostly grants

- ~Any topic related to health/medicine
- Same 3 deadlines each year
- Peer review of proposals

NIH SBIR/STTR Funding by Institute



**FY 2011
SBIR/STTR**

SBIR: \$609 M

STTR: \$ 73 M

Total: \$682 M

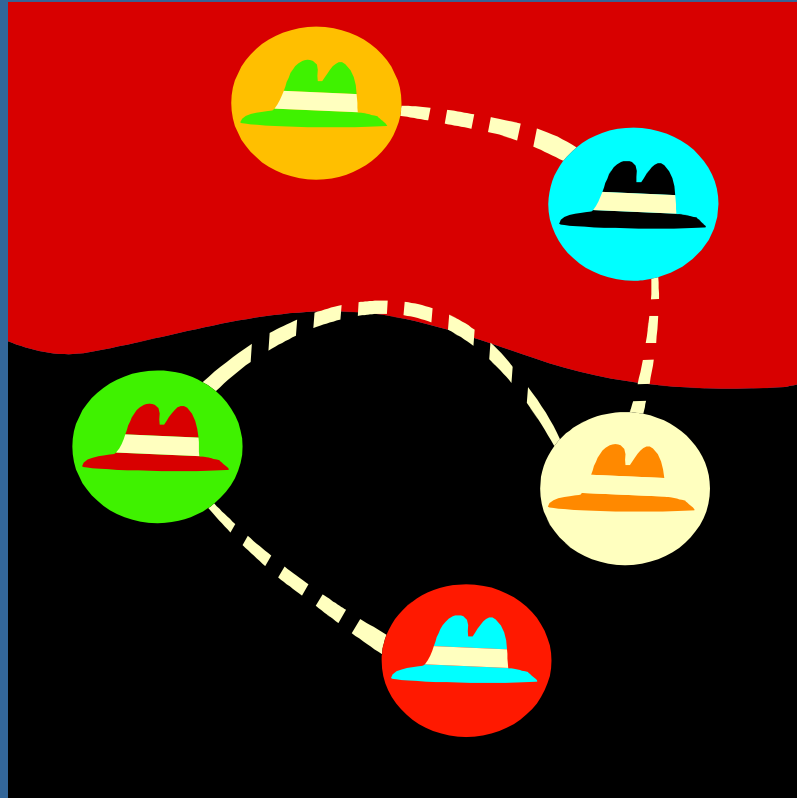
NIH Grant Solicitations

1. “Parent” solicitation: 3 deadlines/yr
 - Yearly list of topics of special interest
2. Special/targeted solicitations

http://grants2.nih.gov/grants/funding/sbir_announcements.htm

 - Some have longer durations, higher budgets
 - 60 active listings – examples:
 - New Technologies for Viral Hepatitis
 - NINDS Exploratory Clinical Trials
 - Novel Technologies for Rapid and Sensitive Biomonitoring in Humans
 - Advanced Neural Prosthetics

2. Strategic Use of SBIR Funds



Without the right strategy, the only thing worse than not getting an award is getting one!

You can turn down an award...



... but it will break your heart.

Using SBIR Funding Strategically

1. Fund high-risk/high-return technology development
2. Establish scientific/technical leadership
3. Gain credibility via successful review
4. Assess market, business opportunity, competitive position
5. Fund consultants and collaborations
6. Define project goals and deliverables
 - Focused expansion rather than “scope creep”
7. Balance costs, benefits and risks
 - *Proposal preparation is not free!*

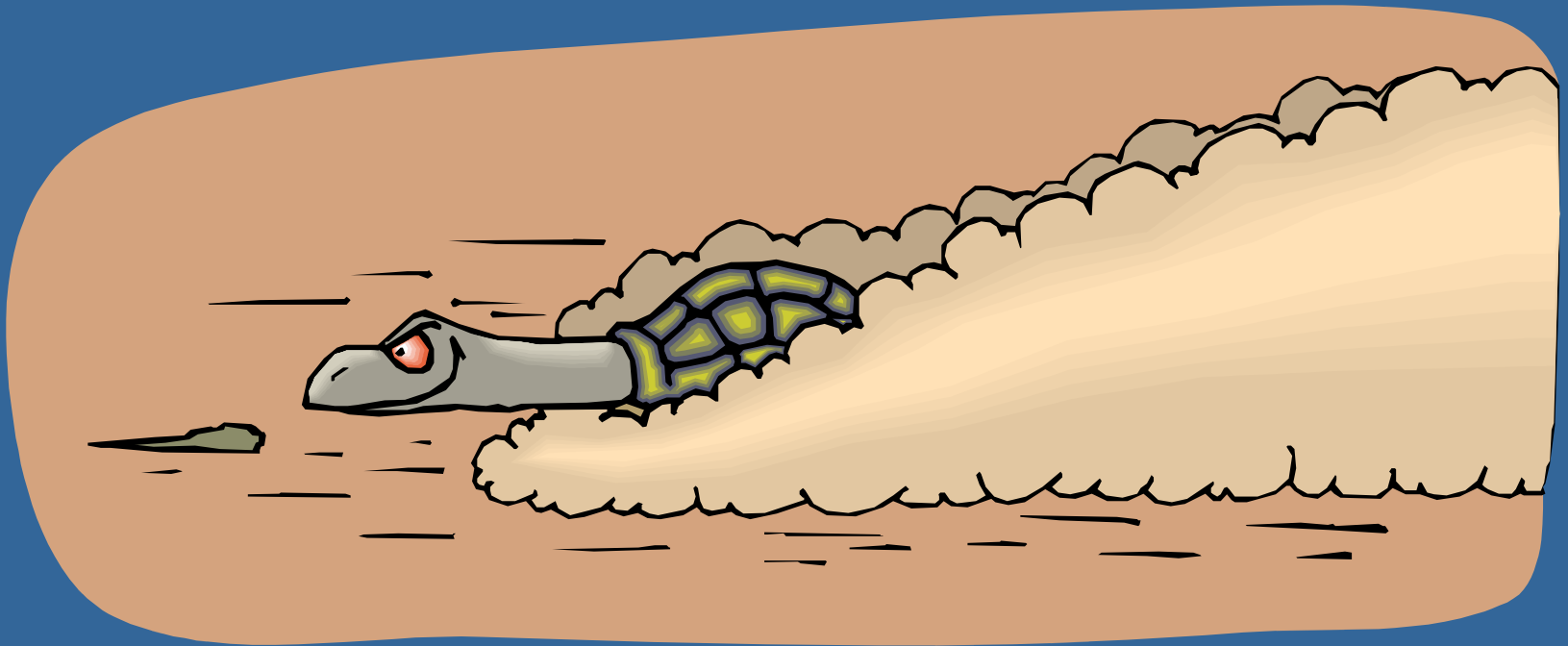
Is this really an SBIR project?

- “*Gee whiz!*”
 - Innovation: Is it a novel innovative technical advance?
- “*Who cares?*”
 - Significance: Will it develop an enabling technology? Advance the state of the art? Create a business opportunity? Solve an important problem?
- “Field of Dreams” (“if you build it, [they] will come”) is for movies, not technology commercialization!

Considerations Before You Start Writing

1. Good match with company strategy and timeline
2. Capabilities
 - Credible PI with experience and expertise
 - Facilities, equipment, resources, established methods
 - Time & resources to prepare competitive proposal
3. Commercial potential
 - Marketable product or service
 - Clear commercialization strategy and pathway
4. Finances: adequacy of proposed budget
5. Intellectual property: patent status, freedom to operate
 - File provisional patent application before submitting grant
 - Ability to describe technology/research without compromising IP position

3. SBIR “Fast-Track” Program



Guess how long...



... it takes to receive
the money after you
apply?

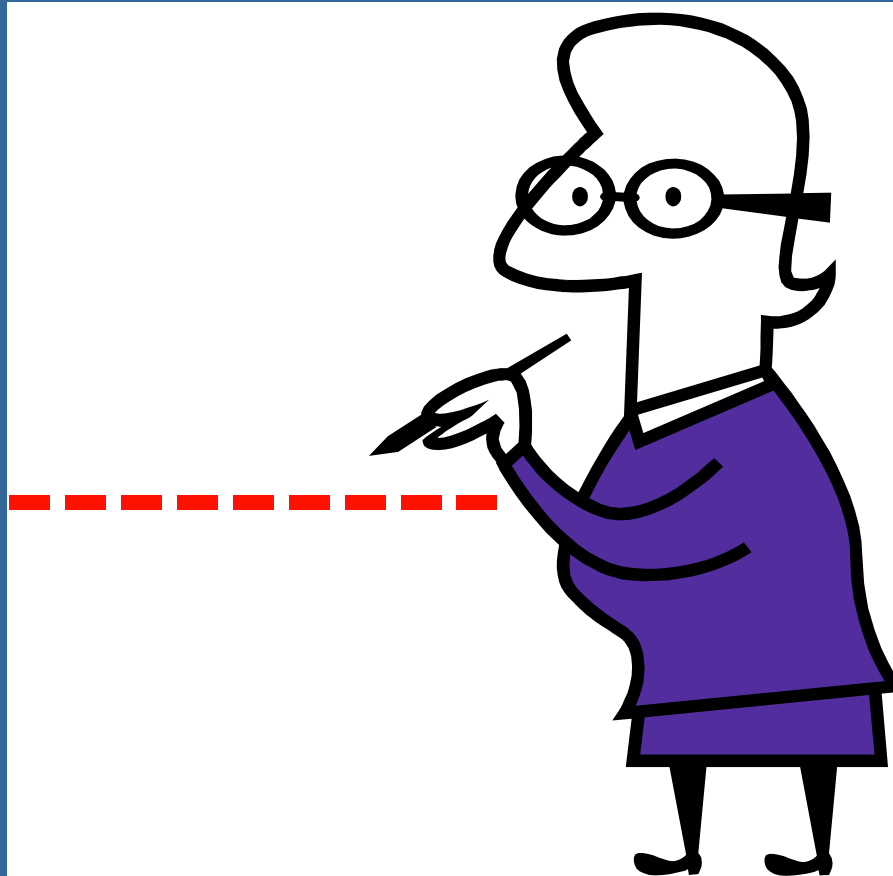
Fast-Track: Expedited Review

- Concurrent review of Phase I and Phase II plans
- Phase II funding contingent on Phase I success
- Phase I/II funding gap reduced

Requirements

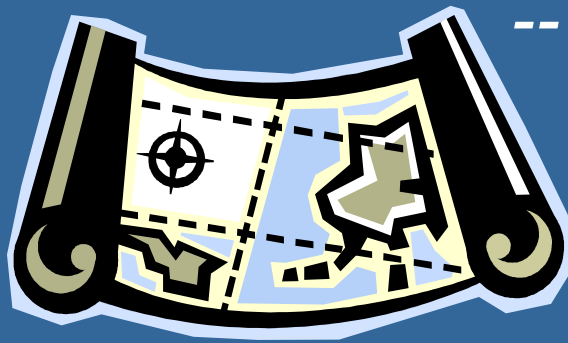
- Clear, measurable milestones in Phase I
- Commercialization plan for Phase II
- Non-federal matching funds (DoD) or commercialization commitment (NIH)
- Compelling, advanced projects with good preliminary data

4. Application Process



If you don't know where you are going, you
will probably end up somewhere else.

-- Laurence Peter



Where Do I Start?

Before you start writing...

1. Complete electronic registrations (4-6 weeks)
2. Download application form & instructions
3. Make the business case: critical unmet need, real market, feasible business strategy
4. Outline the research plan
5. Talk to the NIH program officer
6. Build a complete team, identify collaborators
7. Compile preliminary supporting data

NIH Funding Timetable

Proposal receipt date*	Scientific peer review	Advisory council review	Award date
Apr 5	June/July	Sept/Oct	Nov
Aug 5	Oct/Nov	Jan/Feb	Mar
Dec 5	Feb/Mar	May/June	July

**AIDS/HIV: May, Sept, Jan*

90-Day pre-award costs are allowable, at your own risk.

DoD Funding Timetable

Program	Release Date	Accept Proposals	Closing date (*)
DoD STTR.A	26 Jan	27 Feb	28 Mar
DoD SBIR.2 **	24 Apr	24 May	27 Jun
DoD SBIR.3 **	26 Jul	27 Aug	26 Sep
DoD STTR.B **	26 Jul	27 Aug	26 Sep

* NIH: 5:00 pm local time; DoD: 6:00 am EST

** expected

Guess how ...



... you can benefit
from searching past
grant awards?

Search Past SBIR/STTR Awards

Key-word searching at:

- SBA TechNet (all SBIR/STTR)
- NIH RePORTER (all NIH)

Main Proposal Sections

1. Abstract – project description and narrative
2. Specific aims (1 pg)
3. Research Plan (6 pg Phase I, 12 pg Phase II)
 - A. Significance
 - Critical unmet need
 - Commercial potential & business opportunity
 - Societal benefits
 - (Preliminary studies)
 - B. Innovation
 - C. Research design and methods

Supporting Sections

1. Budget and justification
2. Personnel information
 - Biosketch, personal statement of qualifications
3. Human subjects protection
4. Vertebrate animal care
5. Cover letter
 - Suggest expertise needed for appropriate review
 - Suggest study sections
 - List any individual(s) or organization(s) in conflict
6. Budgets and letters from collaborators, consultants
7. Product Development Plan (Phase II)

Project Budget

1. Direct costs: costs easily identifiable with this project
 - salaries & wages
 - materials & supplies
 - consultants & subcontracts
 2. Indirect costs: fringe benefits, overhead, G&A
 - Phase I, 40%; Phase II, 25% unless organization has a negotiated indirect cost rate.
 3. Fee: 7% of total cost, no restrictions on use
- All costs must be explained in budget justification.
 - Median Phase I total cost (NIH): \$180k



“Sell” Your Proposal

1. Write to the review criteria.
2. Convince reviewers of importance of the problem.
3. Specify novelty, innovation and significance.
4. Articulate the value proposition.
5. Write Specific Aims as an executive summary.
6. Make presentation attractive, easy to read and follow.
7. Don't lose the “big picture” in the details.





I love deadlines. I like the whooshing sound they make as they fly by.

-- *Douglas Adams*

Plan for Contingencies

Deadlines are not flexible.

If you wait until the last possible minute to submit the proposal, what will you do if:

- your ISP goes out of business and you need to receive critical text from your collaborator?
- a car hits a utility pole down the street and your office building loses electricity?
- your collaborator's university wants 2 weeks to review its subaward?
- you find an error in the submitted documents?

Sample R01 Grant Applications

NIAID Examples, caveats*

<http://www.niaid.nih.gov/researchfunding/grant/pages/appsamples.aspx>

1. Summary Statement
2. Full application
 - A. Research plan (R01, not SBIR)
 - * Hypothesis-driven basic research, not commercial R&D
 - R01 research plan: 12 pg, 4 yr project
 - SBIR research plan: Phase 1 - 6 pg, 6 mo project; Phase II - 12 pg; 2 yr project
 - B. * Uses modular budget, rather than detailed budget
 - C. Examples of supporting sections (same for all NIH grants)

5. Review Process



Review Criteria

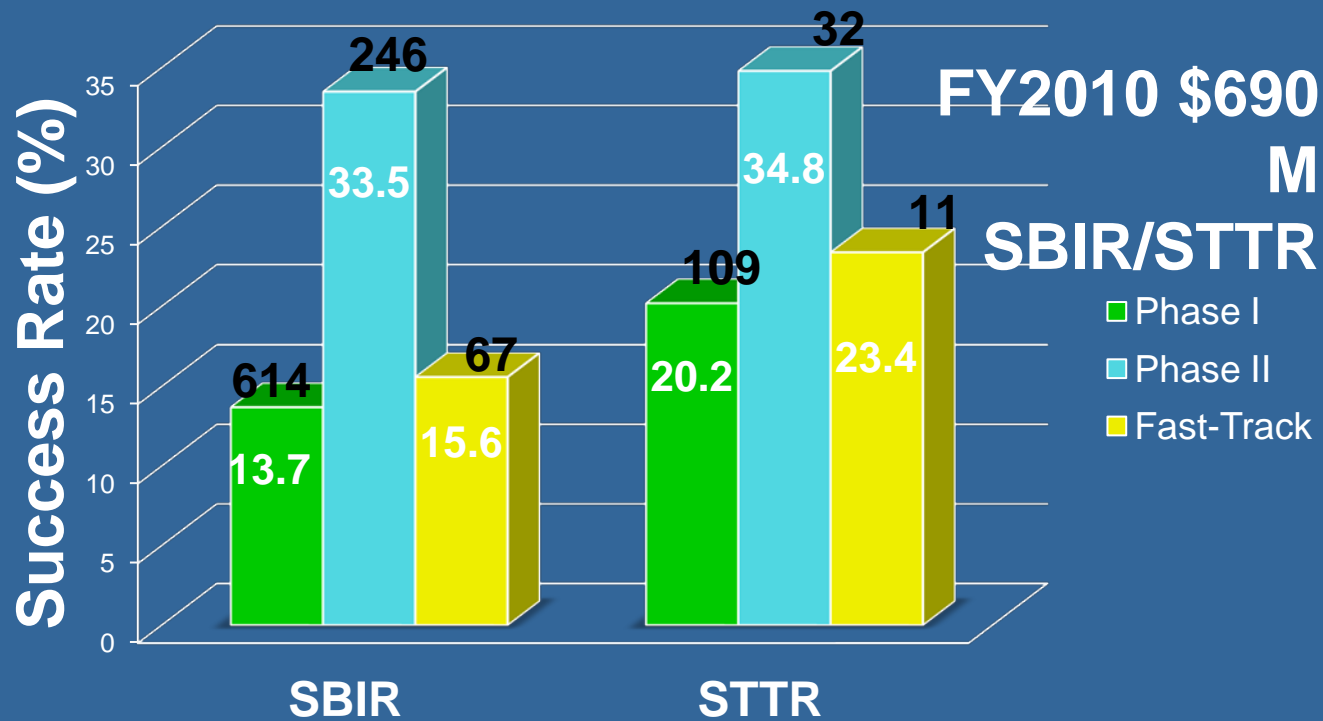
Phase I

- Significance: “who cares?”
 - Critical problem, important scientific contribution, commercial potential
- Investigators: PI and team – record of accomplishments
- Innovation: “gee whiz!” revolutionary, not evolutionary
- Approach:
 - Sound research design, feasible methods
 - Milestones, risks, alternatives
- Environment – facilities and resources

Phase II

- All of above + commercialization plan, letter of interest from potential commercial partner

NIH SBIR/STTR Success Rate



Guess what...



... is the most
common reason for
a low score?

Other Reasons for Low Scores

1. Lack of clear objectives, end-points and success criteria
2. Unfocused or poorly described research plan
 - Unrealistically large amount of work proposed
 - Uncritical experimental approach
 - Lack of innovation
 - Low commercial potential or societal impact
 - Lack of experience with essential methodologies
 - Unfamiliar with state of the art and published work
 - Inadequate data and statistical analysis

You May Resubmit (Once)!

1. Talk to program manager
2. If reviewers do not accept premise or commercial potential: hard to overcome objections
3. Respond to specific criticisms: 1-pg Introduction
4. Mark revisions in text
5. Update letters, biosketches
6. Use correct application form
7. Submit for next deadline

6. Conclusions



Top 10 Tips

1. A good idea is necessary but not sufficient.
2. Grant writing is a “sales” activity, customer = reviewer.
3. Use charts, tables, flow charts, diagrams, photos, etc.
4. Make the proposal readable: short paragraphs; major point of paragraph = the lead sentence; easy to follow.
5. Use correct grammar and spelling; avoid jargon.
6. Describe specific quantitative success criteria.
7. Use internal peer review to check content, style and typos.
8. Plan, plan, plan – before you start writing.
9. Start early to complete registrations.
10. Follow the directions.

Take-Home Message

1. **Free money:** non-dilutive funding for technology R&D leading to commercial product or service.
2. Funded collaborations can expand the scope of expertise and capabilities.
3. Proposals need to SELL the program, the commercial solution and your ability to deliver.





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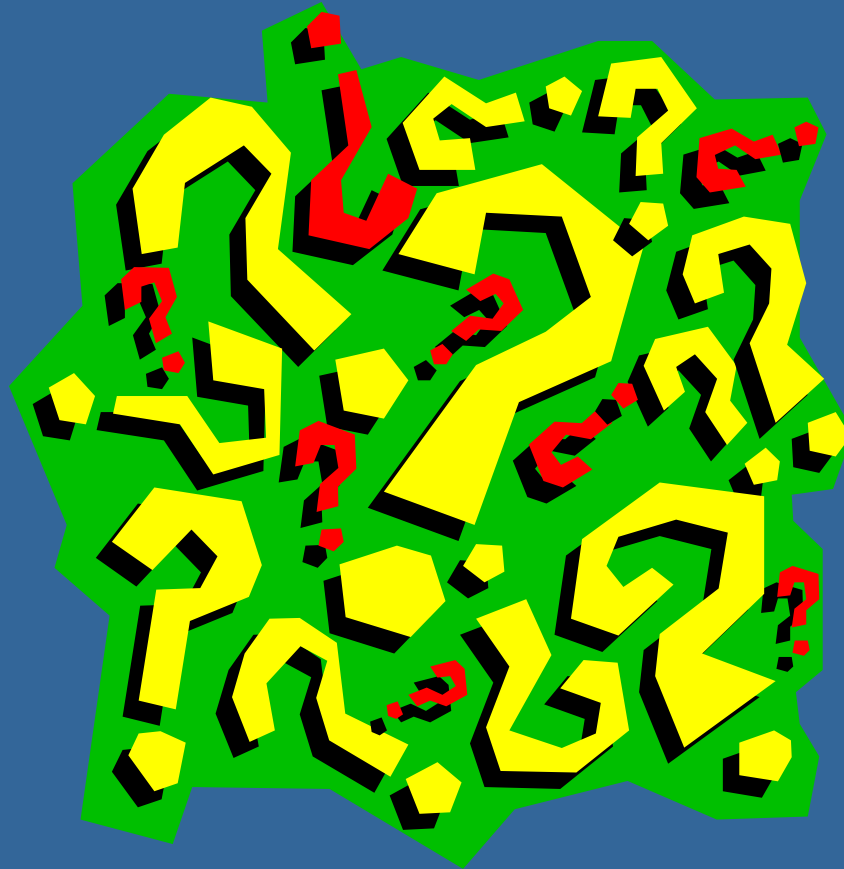


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7. Information Sources



General SBIR Information - NIH

- NIH SBIR home page:
<http://grants.nih.gov/grants/funding/sbir.htm>
 - General info, presentations: bottom of page
- Targeted solicitations:
http://grants2.nih.gov/grants/funding/sbir_announcements.htm
- NIH SBIR/STTR study sections:
http://www.csr.nih.gov/Roster_proto/SBIR_section.asp
 - Other special emphasis study sections:
http://www.csr.nih.gov/Roster_proto/allother_sep.asp

Electronic Registration

1. DUNS (Data Universal Numbering System)
 2. CCR (Central Contractor Registry Database)
 3. Grants.gov
 4. eRA Commons (NIH ONLY)
-
- Allow 4-6 weeks
 - Directions and links: Sections 1.1 and 2.2, SBIR/STTR Application Guide

Omnibus NIH Solicitations

- 2012 Parent SBIR [R43/R44]: PA-12-088, <http://grants.nih.gov/grants/guide/pa-files/PA-12-088.html>
- 2012 Parent STTR [R41/R42]: PA-12-089 , <http://grants.nih.gov/grants/guide/pa-files/PA-12-089.html>
- Application Guide (Instructions), http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_VerB.pdf

*** Always check latest updates.*

SBIR Information: DoD, NSF

- DoD SBIR
 - Home page: <http://www.acq.osd.mil/osbp/sbir/>
 - Follow “Get Started Now” link,
<http://www.acq.osd.mil/osbp/sbir/sb/getting-started-phase-1.shtml>
- NSF SBIR home page:
<http://www.nsf.gov/eng/iip/sbir/>
- Sample applications (may be outdated):
http://www.sbir.dsu.edu/sbhti/home/proposal_preparation/sample_proposals/samples.htm

Search Past SBIR/STTR Awards

Key-word searching at:

- SBA TechNet (all SBIR/STTR):

http://tech-net.sba.gov/tech-net/public/dsp_search.cfm

- NIH RePORTER (all NIH):

<http://projectreporter.nih.gov/reporter.cfm>

SBIR: Phase 1= R43, Phase 2=R44

STTR: Phase 1= R41, Phase 2=R44

General SBIR Web Sites

1. SBA: <http://sbir.gov/>
2. SBIR gateway, all agencies:
<http://www.zyn.com/sbir/>

Information for all SBIR programs:

- Links to individual agency SBIR web pages
- Updated information and application forms
- List of application deadlines for all agencies.
<http://www.zyn.com/sbir/scomp.htm>
- ** Consolidated topic search for all agencies,
<http://www.zyn.com/sbir/sbres/sbcss.htm>

Examples: Supporting Documents

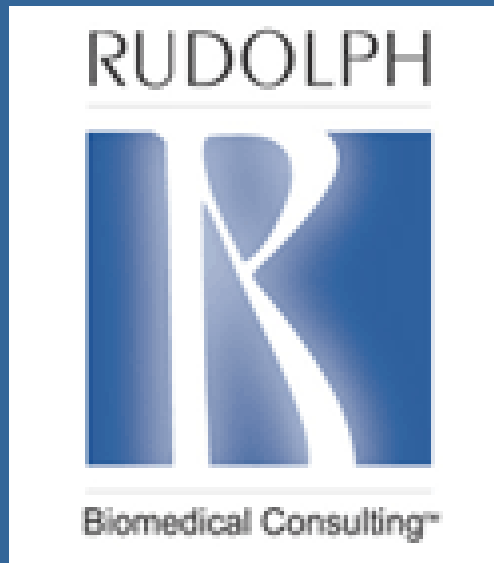
NIH Supporting Documents - NIAID

Although these are described for basic research grants, the same documents are required for SBIR/STTR grant applications

<http://www.niaid.nih.gov/researchfunding/grant/pages/samples.aspx>.

Proposal Preparation Advice

1. Gregory Milman (some advice may be dated), Advice Presentations for SBIR and STTR,
<http://www.niaid.nih.gov/researchfunding/sb/pages/pres.aspx>
2. NIH eSubmission Tips for Small Business Applicants,
http://grants.nih.gov/grants/electronicreceipt/files/NIH_eSubmission_SmBus_Tips.pdf
3. NIH: Avoiding Common Errors,
http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm



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